In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-0173V

Filed: 31 March 2010

MICHAEL and ANDREA BANKS, as the Legal Representatives of their Minor Daughter, EMILY BANKS,	*	
Petitioners,	*	
v.	*	**UNPUBLISHED DECISION**[1]
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Curtis R. Webb, Esq., Webb, Webb & Guerry, Twin Falls, Idaho, for Petitioner;
Darryl R. Wishard, Esq., United States Department of Justice, Washington, District of Columbia, for Respondent.

RULING ON ENTITLEMENT
BASED UPON THE WRITTEN RECORD
AND DISMISSAL DECISION

ABELL, Special Master:

On 17 March 2008, Petitioners filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"),[2] alleging that their daughter Emily

[1] This opinion constitutes my final "decision" in this case, pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Therefore, unless a motion for review of this decision is filed within 30 days after the time given herein to Petitioner to make such filing has elapsed, the Clerk of this Court shall enter judgment in accord with this decision. Moreover, Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of decision within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

suffered the onset of seizures and developmental delay, and that such was related to the administration of the Diphtheria-Tetanus-acellular Pertussis (DTaP) and pneumococcal conjugate (PCV) vaccines administered to her on 1 April 2005, and that her developmental delay was significantly aggravated by her receipt of the Measles-Mumps-Rubella (MMR) vaccine on 9 December 2005. Petition (Pet.) at 1. As an alleged vaccine-related injury, Petitioner demanded compensation for unreimbursable expenses for past or future treatment, pain and suffering, and attorney's fees and costs. This Court is jurisdictionally invested with the task of determining whether Petitioner is entitled to compensation. Due to the lack of substantiating proof of the types statutorily-required and amounting to a preponderance of the evidence, the Court denies compensation.

I. PROCEDURAL HISTORY

Petitioner was represented by able counsel, and filed all of the relevant medical records relating to Petitioner's alleged condition. See Petitioner's Exhibits ("Pet. Ex.") 1-21. Respondent filed its Report, pursuant to Rule 4(c), on 29 May 2009, denying compensation. After sincere attempts throughout calendar year 2008 to engage a thoroughgoing, explanatory medical expert to opine in support of the Petition, Petitioner moved on 10 October 2008 for a ruling on the written record, and the Court hereby grants that motion.

II. FACTUAL RECORD

Emilywas born 3 December 2004, having had a normal gestation and birth, and was assessed normal at her newborn examination. Pet. Ex. 1. She received her first Hepatitis B vaccine the day she was born and her first DTaP and PCV vaccines a little over a month later, all without incident. *Id*.; Pet. Ex. 2 at 1. A little over two months later, on 1 April 2005, Emily was administered her second DTaP and PCV vaccines. Pet. Ex. 2 at 2.

The next day, 2 April 2005, Emily's father noticed her eyes and head twitching, which persisted for two to four minutes, after which she fell asleep. Pet. Ex. 2 at 2. She was taken back to her doctor a couple of days later, who identified the phenomenon as a seizure but indicated "no pertussis." *Id*. Further examination gave rise to differential diagnoses, but Emily's vaccination was not included in that analysis, after having been ruled out. Pet. Ex. 2 at 10. Without any contraindications, Emily received her third DTaP and PCV vaccinations on 13 June 2005. Pet. Ex. 2 at 3.

Until 27 July 2005, Emily suffered no further seizures, but did experience some brief shuddering spells, and began to reveal more developmental delay. *Id*; Pet. Ex. 2 at 15-17. On 27 July 2005, after visiting the doctor's office, she suffered a 3.5 minute seizure, leading to an increase in her anti-seizure medication, but no noticeable side effects. Pet. Ex. 2 at 15-22. She had no further seizures between July and mid-December 2005, and was diagnosed in November of that year with global developmental delay without regression. *Id*.

Her global developmental delay, affecting her physical and neurological growth, continued for the next few years to remain the primary concern in her course, whereas her seizures remained fairly controlled, only emerging once every several months. She continued to receive vaccinations according to her prescribed schedule. She was eventually treated for spastic cerebral palsy. Pet. Ex. 2 at 67-68.

III. DISCUSSION

This Court is given jurisdiction to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a listed Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). For certain categories of vaccines, the Vaccine Injury Table lists specific injuries and conditions, which, if found to occur within the period prescribed therein, create a rebuttable presumption that the vaccine(s) received caused the injury or condition. §14(a). The vaccines which Petitioner alleges to have caused her condition(s) were the Td vaccine, listed under categories I on the Vaccine Table. None of the conditions complained of by Petitioner are associated with Td on the Vaccine Table. 42 C.F.R. § 100.3(a). Essentially, this relegates Petitioner's claim to an "actual causation" theory of relief, under which Petitioner must prove that such vaccine actually caused the injury(ies) alleged.

First, on the claim for the Table presumption of causation, Petitioners do not claim that Emily suffered from an encephalopathy as a consequence of her DTaP vaccination, but the Court considers it for the sake of being thorough. The term "Encephalopathy"is a listed Table Injury, corresponding to categories II and III. 42 C.F.R. § 100.3(a). That means that, if the Court were to find that Emily actually suffered an encephalopathy (as defined in the Table's Qualifications and Aids to Interpretation) within 72 hours of receiving the DTaP vaccine, Petitioners would be entitled to a presumption that the vaccine caused that condition, requiring Respondent to prove that the condition was caused by a factor unrelated, lest Petitioners prevail on the issue of entitlement. §§11(c)(1)(C)(i) and 13(a)(1)(A)-(B). In finding facts to support or oppose a finding that Emily's condition fits the Table definition of encephalopathy, the Undersigned is directed by the Statute to consider "relevant medical and scientific evidence," to include "any diagnosis, conclusion, [or] medical judgment...contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, [or] condition," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." §13(b)(1)(A)-(B). Of course, these sources are not mechanistically determinative, and the Undersigned may consider other portions of the record so as to view the record "as a whole" in arriving at particular factual findings. §13(b)(1)-(2).

The Vaccine Table's Qualifications and Aids to Interpretation (QAI) posits that an encephalopathy sufficient to be granted the statutory presumption must manifest within 72 hours of vaccination. 42 C.F.R. § 100.3(a)(II)(B). For an encephalopathy to meet the criteria of the Table, it must present acutely and ultimately prove fatal or chronic. § 100.3(b)(2). Further, as to what constitutes an acute encephalopathy in Francesca's situation, "an acute encephalopathy is one that is sufficiently severe so as to require hospitalization ... [and] is indicated by a significantly decreased

level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i). The phrase "significantly decreased level of consciousness" is also a defined term in the QAI. Such state is "indicated by the presence of at least one of the following clinical signs lasting 24 hours or more: (1) Decreased or absent response to environment...(2) Decreased or absent eye contact...or (3) Inconsistent or absent responses to external stimuli. 42 C.F.R. § 100.3(b)(2)(i)(D). The QAI adds, furthermore, that "Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy." 42 C.F.R. § 100.3(b)(2)(i)(E).

Based upon the medical records and other materials filed in this case, it does not appear that Emily suffered an encephalopathy fitting the Table definition within the 72 hours following any of her DTaP vaccinations. Nothing in the medical records indicates a persistent decreased level of consciousness meeting the Table definitions. Given the contents of Emily's medical records, the Court cannot find by a preponderance that she suffered from an encephalopathy within the period prescribed by the Vaccine Table in order to apply the Table presumption of causation.

Secondly, the medical records do not support a causative connection between the vaccination administered and the injuries suffered under an actual causation burden of proof. Under the statute, the Court cannot grant a petitioner compensation based solely on the petitioner's asseverations. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not manifestly support the Petitioners' claim, a medical opinion must be offered in support. No medical expert opinion report was filed by Petitioner to support the claims of causation within the Petition to a preponderance of the evidence, and Petitioner therefore did not surmount the standard set by the settled law on this point. Accordingly, the information on the record extant does not show entitlement to an award under the Program.

A petition may prevail if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury or condition complained of. *See* § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit has articulated its three-part actual causation analysis as follows:

> [A petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the

vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury leading to Petitioner's condition, he must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (1994).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (2006) (emphasis added), citing *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir.1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that the injured party would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*.

Here, Petitioners have not filed medical records or offered medical expert testimony to proffer, let alone explain, a "medical theory causally connecting the vaccination [to] the injury." Certainly absent was a detailed analysis of the Record to indicate a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." As such, Petitioners have not offered a theory of causation as such, but this is certainly not due to lack of opportunity to present a medical expert opinion. There has not been demonstrated to the Court a "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," *Q.E.D. See Althen, supra*.

In short, Petitioners have not met the burden of proof set forth in the Act.[3] Petitioners have presented none of the evidence required by the Act in the form of corroborative medical records, and failed to account for the contrary explanations set forth in the medical records that contradicted their contentions.

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[3] *See Raley v. Secretary of HHS*, No. 91-0732, 1998 WL 681467 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) (stating "[t]he requirement that [a] petitioner['s] claims must be supported either by medical records or medical expert opinion simply addresses the fact that the special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone"); *Bernard v. Secretary of HHS*, No. 91-1301, 1992 WL 101097 (Fed. Cl. Spec. Mstr. Apr. 24, 1992) ("The medical significance of the facts testified to by the lay witnesses must be interpreted by a medical doctor, who, in turn, expresses the opinion either that a compensable Table injury has occurred or that the vaccine in question actually caused the injury complained of. If such an opinion appears in the medical records, then it is unnecessary to call a retained expert witness in order to establish a prima facie case; if, on the other hand, the medical records do not provide such substantiation, then a petitioner must retain a medical doctor who, upon review of the entire record, concludes that it is more likely than not that a compensable injury has occurred.").

IV. CONCLUSION

Therefore, in light of the foregoing, no alternative remains for this Court but to **DISMISS** this petition with prejudice. In the absence of the filing of a motion for review, filed pursuant to Vaccine Rule 23 within 30 days of this date, the clerk shall forthwith enter judgment in accordance herewith. **IT IS SO ORDERED.**

Richard B. Abell
Special Master